

**SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
JULY 10, 2002**

The On-Site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, July 10, 2002 at 9:00 a.m. Eastern Daylight Time (EDT) as part of the Eighth Annual NELAC Meeting in Tampa, Florida. Chairperson Alfredo Sotomayor of the Wisconsin Department of Natural Resources led the meeting. The Action Items are shown in Attachment A. The list of participants is given in Attachment B. The purpose of the meeting was to address items of importance that follow.

INTRODUCTION

Mr. Sotomayor called the meeting to order by introducing himself as the Committee's Chair. He asked the other Committee members to introduce themselves as well. Mr. Sotomayor then reviewed the session agenda. Because some Committee members had to attend other sessions, he asked that attendees be aware of the time allotted to each agenda item and that any topic not fully covered would be moved to the "parking lot".

CONFIDENTIAL BUSINESS INFORMATION (CBI) - SECTION 3.4.5

Richard Sheibley gave a brief background regarding why the Committee felt it needed to revise this section in the Standards. He mentioned that all current accrediting authorities are states, which have laws concerning CBI, freedom of information, and "right to know". The accrediting authorities are subject to those laws and rules. The Committee, therefore, revised the Standard to reflect that state laws have applicability in handling NELAC documents obtained during an on-site assessment. The Committee retained references to the Federal CBI regulations and redefined their applicability.

The purpose of this section is to guarantee that contractual obligations between a laboratory and its client can be maintained. Attendees agreed that this section is important to include in the Standards. Most assessors are not familiar with CBI practices. Because of inconsistencies among assessors regarding the implementation of CBI practices, training is required. Not only should assessors be trained on how to handle CBI, but laboratories also need to be informed regarding what is considered to be CBI. The On-Site Assessment Committee will review suggestions and comments at future meetings and discuss possible solutions.

A question was posed regarding which states' CBI regulation would apply if the primary accrediting authority were a different state than that of the laboratory being assessed. Would both states' regulations need to be incorporated into the CBI procedure? Mr. Sheibley responded that documents and materials would be stored in the state of the primary accrediting authority and that the laws of that state would govern CBI and how it should be handled.

BIOLOGICAL TECHNICAL DISCIPLINES FOR ASSESSOR TRAINING - SECTION 3.2.3.2

Dr. Faust Parker noted that the intent of this section was to reflect the information in Chapters 2 and 5 of the Standards.

A suggestion was made to add LC/MS to the list of Organics under section 3.2.3.2.

An attendee inquired whether or not NELAC provides training for assessors. It is NELAC's responsibility to develop the Standards for training, not to provide the training itself. Accrediting Authorities in turn, approve training programs for their assessors. The Committee hopes to publish outlines for types of training on the website and instrument manufacturers could add additional information that would be important for assessors. Nobody has offered to provide technical training yet. Training providers or technical experts are welcomed to set up courses to train assessors. Classes should teach assessors what to look for in data, how to review data, and what the data should look like.

Mr. Sotomayor mentioned that technical training is discussed further in Appendix B, which was made effective immediately, with the hope that someone would acknowledge it and start offering technical training. It was also noted that with the restructuring of NELAC, it would be possible that other entities might provide training courses to assessors.

APPENDIX C

Mr. Sotomayor preceded discussion on Appendix C by thanking all those who worked so diligently to complete it. He especially wanted to thank Mimi Uhlfelder who was not able to attend the Conference and who would be rotating out of the Committee.

Section C.1

Daniel Hickman noted that a version of Appendix C was presented at NELAC 7 as Appendices C and D. A workgroup was established by the NELAP AAs, which offered suggestion on the then existing appendices. The Committee combined the two appendices along with new language to arrive at the currently proposed Appendix C. He also wanted to bring to the attention of the attendees that paragraph two states that: "At a **minimum** the following elements shall be included in the SOPs..."

An attendee asked what needed to be included with the signature log. Mr. Hickman responded that the log should identify each analyst by his/her signature and initials. Personnel files will track when the analyst arrived and departed from the laboratory. Mr. Hickman noted that the mention of a signature log in Appendix C references language in Chapter 5 of the Standards. A suggestion was then made to include references in Appendix C to corresponding sections in other chapters in the Standards. Although the Committee felt this to be a good suggestion, the amount of time required to make all necessary references would be too extensive for Committee members. Moreover, as Chapter 5 is revised, all cross-references would need to be revised. Therefore, unless an outside party is willing to perform this task, the Committee will not provide the cross-references.

Section C.2

An attendee asked whether section C.2.3.2 and the list that follows this section is completed before or during the assessment. Discussion ensued regarding what the original intent of the language was and whether or not it should be changed. To make this section clearer, Committee members and attendees agreed that section C.2.3.2 should read:

The laboratory documents review process, to be performed before and/or during the on-site phase of each assessment, shall include the following records:

Section C.3

The changes to this section were accepted as proposed with no further modifications.

Section C.4

Marlene Moore noted that this section in Appendix C was originally part of Appendix D. It specifies the minimum performance elements of the test methods and procedures for the evaluation during on-site assessments that must be included in the accrediting authority's SOP. Many comments were received at NELAC 7i regarding this section and the Committee incorporated as many as possible to comprise the proposed changes to the section.

Some attendees were confused with the language of section C.4.2 regarding the three phases and what was required for each phase. Ms. Moore explained that in phase I, as a pre-assessment, assessors need to review all SOPs. In phase II, the assessor may choose which SOPs to audit on-site. This will give assessors the ability to use their discretion in what they check. Attendees noted that because of the loose structure of this language, not all procedures and methods might be checked over several assessments. The Committee will draft language to address this issue in future teleconferences.

An attendee noted that section C.4.2.1.1 conflicts with Chapter 6, section 6.2.3. A laboratory might not be seeking accreditation for every test it performs, however, the section states that laboratories need to document **all** tests they perform. Committee members agreed that this language should be clarified. Section C.4.2.1.1 will be changed to:

Document all tests for which the laboratory requests or maintains accreditation.
~~performed by a laboratory.~~

A participant questioned the language in section C.4.2.2 regarding the elements assessors needed to evaluate during an on-site assessment. The intent of the Committee was to ensure that the assessor would inspect areas where test methods are performed, which was not clear from the proposed language. It was suggested and agreed upon that C.4.2.2 should read:

C.4.2.2 Phase II – Verification of Proper Execution of Test Methods

Assessors must verify that analysts complete performance elements of test methods and determine whether analysts adhere to laboratory SOPs or Methods Manuals by inspecting areas where test methods are performed and:

Along with the change in C.4.2.2, an attendee asked what an assessor should do if an analyst were not present during the assessment. It was agreed to change C.4.2.2.3, for further clarification, to read:

~~C.4.2.2.3 Inspecting areas where test methods are performed.~~

C.4.2.2.3 Interviewing authorized laboratory representatives when analysts are unavailable.

Section C.5

The Committee knows that there has been confusion over the definitions of “findings”, “deficiencies”, and “observations”. The Committee is currently working on clarifying these definitions and they will be presented at NELAC 9.

Section C.6

Many comments were made regarding recommendations from assessors given to laboratories during the on-site assessment. Most laboratories would like recommendations from the assessor so they can make improvements, but to prevent liability, assessors usually do not make recommendations. Most assessors avoid this issue by making verbal, rather than written, recommendations. This protects the assessor while helping the laboratory to improve. Committee members as well as attendees feel that this issue needs to be addressed, and has therefore been put in the parking lot.



ASSESSOR'S ELECTRONIC FORUM

David Friedman noted that the Committee listened to the concerns raised at NELAC 7i regarding consistency of assessments. The Committee wanted to address this issue more proactively and have thus decided to hold an assessor's electronic forum. The forum will allow assessors to exchange ideas and will inform them of changes made to the Standards. The forum will be held October 15, 2002, from 1:00 p.m. to 4:00 p.m. EDT and will have 80 phone lines and 300 internet connections available. Each state and EPA Region will be given one phone line, with which they can have as many assessors as they wish to be part of the call. Internet connections to the forum are not accessible from an EPA computer. For those not able to participate, all presentations will be archived and accessible via the internet. Mr. Sotomayor has sent a message to the Accrediting Authorities and EPA asking them to identify their assessors. All states are invited to participate, including non-NELAC Accrediting Authorities. Federal assessors will be invited to participate as well.

Mr. Friedman opened the floor for comments and suggestions regarding the assessor's electronic forum. The following suggestions, comments, and clarifications were made:

- Prepare presentations at least a week before the forum and download all material in case of any technical difficulties that might arise during the forum.
- Use www.freeconference.com, which does not charge a fee and can have 200-300 phone lines available.

- ACIL did a survey of assessors a few years ago that might provide information. The Committee should take a look at this survey for further ideas.
- All presentations should be on a central computer that serves all the community functions.
- Only visual material will be archived on the NELAC website, not audio.

Mr. Friedman mentioned that the Committee would like to have four forums per year, three electronically and one in person. The Committee would like to require assessors to participate in a forum as part of their refresher course requirements.

EXPERIENCES AND CONCERNS WITH LABORATORY ASSESSMENTS

Mr. Sotomayor opened the floor to any concerns or comments regarding laboratory assessments or issues not previously mentioned. The following were offered:

- Some assessors depart from the assessed laboratory early, leaving someone else in their place to conduct the closing conference. The remaining assessor may always answer questions from the laboratory regarding deficiencies cited. It was recommended that language regarding this issue be drafted and added to the Standards.
- A question was asked regarding complaints and where they should be directed. Committee members stated that complaints should be addressed to the director of NELAC as well as to the accrediting authority.
- Auditors often do not have time to discuss the findings with the laboratory after the audit has been completed.
- There is still lack of consistency among assessors. Laboratories that are being operated in the exact same way are being cited for different deficiencies in each place. The Committee suggested sending those inconsistencies to Mr. Sotomayor, who will make a list of items to discuss at the assessor's electronic forum.
- A participant questioned how accrediting authorities ensure that laboratories had implemented corrective action and maintained those corrections after the conclusion of the assessment process.
- Accrediting authorities would like to hear complaints regarding their assessors so they can be corrected. There is a requirement in the Standards that assessors provide the laboratory with an assessment appraisal form after an assessment. Laboratories should fill these forms out and return them to the accrediting authority.

- In Louisiana, assessors cannot leave the laboratory without answering every question the laboratory poses regarding the assessment. Each member of the assessment team is also aware of what everyone else on the team is doing so that if someone has to leave early, the remaining assessors can still answer any questions.
- A participant questioned whether assessors were looking for improper practices and data integrity during on-site assessments. If not, language should be drafted to require assessors to do this. Committee members felt this issue should be moved to the parking lot.

ADJOURNMENT

Mr. Sotomayor thanked Mr. Friedman, who will be rotating off the Committee, for all of his invaluable service and hard work. Mr. Sotomayor then thanked participants for attending and adjourned the meeting.

**ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
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Item No.	Proposed Date	Action Item	Date to be Completed
1	7/10/02	The Committee will review suggestions and comments regarding laboratory and assessor training of CBI procedures as well as minimum technical qualifications for assessors at future meetings and discuss possible solutions.	Open
2	7/10/02	The Committee will review how to assure that all procedures and methods will be evaluated during return on-site assessments over time.	Open
3	7/10/02	Committee members will draft definitions for “findings”, “deficiency”, and “observation”.	NELAC 8i
4	7/10/02	Committee members will discuss whether or not assessors may make recommendations for corrective action to laboratories during the on-site assessment.	Open
5	7/10/02	The Committee will discuss how to evaluate data integrity during an on-site assessment.	Open

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ON-SITE ASSESSMENT COMMITTEE MEETING
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